

## General

### Title

Androgen deficiency: percentage of male patients aged 18 years and older with androgen deficiency who are receiving testosterone therapy, who have a hematocrit or hemoglobin test performed within two to six months after initiation of testosterone therapy.

### Source(s)

Endocrine Society. Diagnosis, treatment, and follow-up of men with androgen deficiency. Physician performance measurement set. Washington (DC): Endocrine Society; 2012 May. 17 p. [31 references]

## Measure Domain

### Primary Measure Domain

Clinical Quality Measures: Process

### Secondary Measure Domain

Does not apply to this measure

## Brief Abstract

### Description

This measure is used to assess the percentage of male patients aged 18 years and older with androgen deficiency who are receiving testosterone therapy, who have a hematocrit or hemoglobin test performed within two to six months after initiation of testosterone therapy.

### Rationale

Testosterone-treated men were nearly four times more likely than placebo treated men to experience hematocrit greater than 50% and the risk for a clinically significant increase in hematocrit increases with age (Bhasin et al., 2001; Calof et al., 2005). Men with a pre-treatment hematocrit of greater than 50% are also at increased risk of erythrocytosis (Coviello et al., 2008). Monitoring of hematocrit in men on testosterone replacement can identify individuals who develop erythrocytosis and prevent its medical consequences.

Although the guidelines specify hematocrit measurement, documentation of hemoglobin measurement as a surrogate for identification of erythrocytosis is deemed adequate to meet the requirements of this accountability measure.

Ideally, hematocrit or hemoglobin test should be completed within 2 to 3 months after initiation of testosterone therapy.

#### Supporting Guideline:

The Endocrine Society recommends determining hematocrit at baseline, at 3 months and then annually. If hematocrit is greater than 54%, stop therapy until hematocrit decreases to a safe level, evaluate the patient for hypoxia and sleep apnea, and reinitiate therapy at a reduced dose (Bhasin et al., 2010).

## Evidence for Rationale

Bhasin S, Cunningham GR, Hayes FJ, Matsumoto AM, Snyder PJ, Swerdloff RS, Montori VM, Task Force, Endocrine Society. Testosterone therapy in men with androgen deficiency syndromes: an Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab*. 2010 Jun;95(6):2536-59. [151 references] [PubMed](#)

Bhasin S, Woodhouse L, Casaburi R, Singh AB, Bhasin D, Berman N, Chen X, Yarasheski KE, Magliano L, Dzekov C, Dzekov J, Bross R, Phillips J, Sinha-Hikim I, Shen R, Storer TW. Testosterone dose-response relationships in healthy young men. *Am J Physiol Endocrinol Metab*. 2001 Dec;281(6):E1172-81. [PubMed](#)

Calof OM, Singh AB, Lee ML, Kenny AM, Urban RJ, Tenover JL, Bhasin S. Adverse events associated with testosterone replacement in middle-aged and older men: a meta-analysis of randomized, placebo-controlled trials. *J Gerontol A Biol Sci Med Sci*. 2005 Nov;60(11):1451-7.

Coviello AD, Kaplan B, Lakshman KM, Chen T, Singh AB, Bhasin S. Effects of graded doses of testosterone on erythropoiesis in healthy young and older men. *J Clin Endocrinol Metab*. 2008 Mar;93(3):914-9. [PubMed](#)

Endocrine Society. Diagnosis, treatment, and follow-up of men with androgen deficiency. Physician performance measurement set. Washington (DC): Endocrine Society; 2012 May. 17 p. [31 references]

## Primary Health Components

Androgen deficiency; testosterone therapy; hematocrit; hemoglobin

## Denominator Description

All male patients aged 18 years and older with androgen deficiency who are receiving testosterone therapy (see the related "Denominator Inclusions/Exclusions" field)

## Numerator Description

Patients who have a hematocrit or hemoglobin test performed within two to six months after initiation of testosterone therapy

## Evidence Supporting the Measure

## Type of Evidence Supporting the Criterion of Quality for the Measure

A clinical practice guideline or other peer-reviewed synthesis of the clinical research evidence

A formal consensus procedure, involving experts in relevant clinical, methodological, public health and organizational sciences

A systematic review of the clinical research literature (e.g., Cochrane Review)

One or more research studies published in a National Library of Medicine (NLM) indexed, peer-reviewed journal

## Additional Information Supporting Need for the Measure

In population-based surveys of middle aged and older men, symptoms of low libido, erectile dysfunction, hot flushes, fatigue, loss of vigor, irritability, depressed mood, impaired concentration, reduced physical performance, or sleep disturbance, were associated with low testosterone levels. In these surveys, the prevalence of symptomatic androgen deficiency was approximately 6% of the population of middle-aged to older men and increased with age, waist circumference and poor self-reported health status. Hypogonadism is therefore common in American men, yet only 5% of candidates receive treatment.

According to U.S. Census Bureau (2004) projections, the number of Americans ages 65 or older will rise from approximately 35 million (12.4% of all Americans) in 2000 to nearly 55 million (16.3% of total) by 2020 and nearly 87 million (20.7%) in 2050. In addition to a two-fold increase in the number of elderly patients, octogenarians will comprise the fastest-growing population segment according to age (Batchelor, Jollis, & Friesinger, 1999).

This gap in care can profoundly affect the health of our aging men. Even in younger men with symptoms, infertility may be a consequence of androgen deficiency. Male infertility contributes to 50% of all infertility cases. However, both low testosterone and supraphysiologic androgen administration can lead to infertility. The impaired sperm production that supraphysiological testosterone administration causes is often reversible, but in some series has been shown to take anywhere from 3 months to years.

Inappropriate testosterone use is also a major concern of these times. In the sports arena, so far, 45 National Football League (NFL) players have had a ban or suspension placed on them. Among Major League Baseball players, 7% have tested positive for steroids. This inappropriate use has trickled down to the U.S. population. According to ProjectEAT, a five-year, longitudinal study, overall, 1.5% of adolescents reported using steroids (vandenBerg et al., 2007). In a 2002 study by Texas A&M University, it was estimated that up to 42,000 Texas students were abusing steroids.

It is important that testosterone be used to replace hormonal deficiency, and not be used inappropriately in pharmacological doses for enhancement of physical performance or muscular size. The testosterone process measures listed here will assist us to prescribe testosterone to only those individuals in whom it is medically indicated.

Because the diagnosis and management of androgen deficiency in men poses several challenges (symptoms and signs are nonspecific and modified by age, comorbid illness, severity and duration of androgen deficiency, variation in androgen sensitivity, and previous testosterone therapy; evidence of proper care is weak; long-term health consequences of low testosterone levels are unknown for older men and men with chronic illness; the impact of untreated androgen deficiency on mortality is unclear; the benefits and adverse effects of long-term testosterone therapy on patients are not known), these performance measures were determined to be of critical importance to standardize care as outlined in the clinical guidelines.

## Evidence for Additional Information Supporting Need for the Measure

Batchelor WB, Jollis JG, Friesinger GC. The challenge of health care delivery to the elderly patient with cardiovascular disease. Demographic, epidemiologic, fiscal, and health policy implications. *Cardiol Clin.* 1999 Feb;17(1):1-15, vii. [PubMed](#)

Endocrine Society. Diagnosis, treatment, and follow-up of men with androgen deficiency. Physician performance measurement set. Washington (DC): Endocrine Society; 2012 May. 17 p. [31 references]

U.S. Census Bureau. 2004 interim national population projections. [internet]. Washington (DC): U.S. Census Bureau; 2004 [accessed 2005 Jan 25].

vandenBerg P, Neumark-Sztainer D, Cafri G, Wall M. Steroid use among adolescents: longitudinal findings from Project EAT. *Pediatrics.* 2007 Mar;119(3):476-86. [PubMed](#)

## Extent of Measure Testing

Unspecified

## State of Use of the Measure

### State of Use

Current routine use

### Current Use

not defined yet

## Application of the Measure in its Current Use

### Measurement Setting

Ambulatory/Office-based Care

### Professionals Involved in Delivery of Health Services

not defined yet

### Least Aggregated Level of Services Delivery Addressed

Individual Clinicians or Public Health Professionals

### Statement of Acceptable Minimum Sample Size

Unspecified

### Target Population Age

Age greater than or equal to 18 years

## Target Population Gender

Male (only)

# National Strategy for Quality Improvement in Health Care

## National Quality Strategy Aim

Better Care

## National Quality Strategy Priority

Prevention and Treatment of Leading Causes of Mortality

# Institute of Medicine (IOM) National Health Care Quality Report Categories

## IOM Care Need

Getting Better

Living with Illness

## IOM Domain

Effectiveness

# Data Collection for the Measure

## Case Finding Period

Unspecified

## Denominator Sampling Frame

Patients associated with provider

## Denominator (Index) Event or Characteristic

Clinical Condition

Patient/Individual (Consumer) Characteristic

Therapeutic Intervention

## Denominator Time Window

not defined yet

## Denominator Inclusions/Exclusions

### Inclusions

All male patients aged 18 years and older with androgen deficiency who are receiving testosterone therapy

Note: Refer to the original measure documentation for International Classification of Diseases, Ninth Revision (ICD-9) and Current Procedural Terminology (CPT) coding information.

### Exclusions

Unspecified

### Exceptions

Documentation of patient reason(s) for not performing a hematocrit or hemoglobin test within two to six months after initiation of testosterone therapy (e.g., patient refusal)

## Exclusions/Exceptions

not defined yet

## Numerator Inclusions/Exclusions

### Inclusions

Patients who have a hematocrit or hemoglobin test performed within two to six months after initiation of testosterone therapy

### Exclusions

Unspecified

## Numerator Search Strategy

Fixed time period or point in time

## Data Source

Administrative clinical data

Electronic health/medical record

Paper medical record

## Type of Health State

Does not apply to this measure

## Instruments Used and/or Associated with the Measure

Unspecified

## Computation of the Measure

### Measure Specifies Disaggregation

Does not apply to this measure

### Scoring

Rate/Proportion

### Interpretation of Score

Desired value is a higher score

### Allowance for Patient or Population Factors

not defined yet

### Standard of Comparison

not defined yet

## Identifying Information

### Original Title

Measure #3: hematocrit or hemoglobin test.

### Measure Collection Name

Diagnosis, Treatment, and Follow-up of Men with Androgen Deficiency Physician Performance Measurement Set

### Submitter

The Endocrine Society - Disease Specific Society

### Developer

The Endocrine Society - Disease Specific Society

### Funding Source(s)

Internal funding and commercially supported

# Composition of the Group that Developed the Measure

## Work Group Members:

James Rosenzweig (*Chair*)  
David Aron, MD  
Shalender Bhasin, MD  
Jane Cauley, MD, PhD  
J. Quentin Clemens, MD  
David Cooper, MD  
George Dailey, MD  
Michael Holick, MD, PhD  
Alvin Matsumoto, MD  
George Merriam, MD  
Abraham Morgentaler, MD  
Stephanie Page, MD, PhD

## Work Group Staff:

Stephanie Kutler, Director of Quality Improvement (ES)  
Becky Kresowik, Measure Development Consultant

## Financial Disclosures/Other Potential Conflicts of Interest

The Society's Diagnosis, Treatment, and Follow-up of Men with Androgen Deficiency Performance Measures were developed by a Society work group, under guidance of the Society's Performance Measures Sub-Committee (PMSC) and the Clinical Affairs Core Committee (CACC). All persons in control of content, including all members of the various Society committees, subcommittees and faculty workgroups, as well as staff, disclose all relevant financial relationships of the individual or spouse/partner that have occurred within the last 12 months with any commercial interest(s) whose products or services are related to the content. Financial relationships are defined by remuneration in any amount from the commercial interest(s) in the form of grants; research support; consulting fees; salary; ownership interest (e.g., stocks, stock options, or ownership interest excluding diversified mutual funds); honoraria or other payments for participation in speakers' bureaus, advisory boards, or boards of directors; or other financial benefits. Any conflicts of interest are resolved prior to the individual's control of content, using the peer-review process as the primary mechanism to resolve conflicts.

*At the time of Measure Development - the following Androgen Deficiency Measure Task Force members reported no relevant financial relationships:*

David Aron, MD  
Associate Chief of Staff/Education, Department of Veteran Affairs

Jane Cauley, MD  
Professor, University of Pittsburgh

J. Quentin Clemens, MD  
Associate Professor of Urology, University of Michigan

David Cooper, MD  
Director, Thyroid Clinic, Professor of Medicine, John Hopkins University School of Medicine

George Dailey, MD  
Endocrinologist, Diabetes & Metabolism, Scripps Clinical Medical Group

Alvin Matsumoto, MD  
Professor, Department of Medicine



Acting Head, Division of Gerontology & Geriatric Medicine  
University of Washington School of Medicine

George Merriam, MD  
Physician; Deputy ACOS/R&D, Department of Veterans Affairs

Abraham Morgentaler, MD  
Associate Clinical Professor of Urology, Harvard Medical School

Stephanie Page, MD, PhD  
Associate Professor, University of Washington School of Medicine

James Rosenzweig, MD  
Director of Diabetes Services, Boston Medical Center

*At the time of Measure Development - the following Androgen Deficiency Measure Task Force members reported relevant financial relationships:*

Shalender Bhasin, MD  
Professor & Section Chief, Boston University Medical Center  
Investigator & Consultant, Abbott

Michael Holick, MD, PhD  
Professor of Medicine, Physiology and Biophysics, Boston University School of Medicine  
Investigator & Consultant, Quest; P&G; Novartis; Amgen

Endocrine Society staff associated with the development of content reported no relevant financial relationships.

## Adaptation

This measure was not adapted from another source.

## Date of Most Current Version in NQMC

2012 May

## Measure Maintenance

The developer aims to review the module clinical content and modify as appropriate, based on research and revised clinical practice guidelines

## Date of Next Anticipated Revision

2016 Dec

## Measure Status

This is the current release of the measure.

The measure developer reaffirmed the currency of this measure in June 2016.

## Measure Availability

Source available from [The Endocrine Society Web site](#) .

For more information, contact The Endocrine Society at 2055 L. Street, NW, Suite 600, Washington, DC 20036; Phone: 202-971-3636; Fax: 202-736-9705; Web site: [www.endocrine.org](http://www.endocrine.org) .

## NQMC Status

This NQMC summary was completed by ECRI Institute on April 10, 2015. The information was verified by the measure developer on May 18, 2015. The information was reaffirmed by the measure developer on June 30, 2016.

## Copyright Statement

This NQMC summary is based on the original measure, which is subject to the measure developer's copyright restrictions.

For more information, contact the Endocrine Society at 2055 L. Street, NW, Suite 600, Washington, DC 20036; Phone: 202-971-3636; Fax: 202-736-9705; Web site: [www.endocrine.org](http://www.endocrine.org) .

## Production

## Source(s)

Endocrine Society. Diagnosis, treatment, and follow-up of men with androgen deficiency. Physician performance measurement set. Washington (DC): Endocrine Society; 2012 May. 17 p. [31 references]

## Disclaimer

### NQMC Disclaimer

The National Quality Measures Clearinghouse<sup>®</sup> (NQMC) does not develop, produce, approve, or endorse the measures represented on this site.

All measures summarized by NQMC and hosted on our site are produced under the auspices of medical specialty societies, relevant professional associations, public and private organizations, other government agencies, health care organizations or plans, individuals, and similar entities.

Measures represented on the NQMC Web site are submitted by measure developers, and are screened solely to determine that they meet the [NQMC Inclusion Criteria](#).

NQMC, AHRQ, and its contractor ECRI Institute make no warranties concerning the content or its reliability and/or validity of the quality measures and related materials represented on this site. Moreover, the views and opinions of developers or authors of measures represented on this site do not necessarily state or reflect those of NQMC, AHRQ, or its contractor, ECRI Institute, and inclusion or hosting of measures in NQMC may not be used for advertising or commercial endorsement purposes.

Readers with questions regarding measure content are directed to contact the measure developer.